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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,673	04/03/2001	Brady Esch	CARDE.57307	4482

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EXAMINER

SIRMONS, KEVIN C

ART UNIT	PAPER NUMBER
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3763

13

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,673

Applicant(s)

ESCH ET AL.

Examiner

Kevin C. Sirmons

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-37, 44-47 and 73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-37, 44-47 and 73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Barb reducer lacks proper antecedent basis. The specification supports Barb connector. (claim 29)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27, 28, 33-36, 44-47 and 73 are rejected under 35 U.S.C. 102(e) as being anticipated by Bertolero et al U.S. Pat. No. 5,868,703.

Bertolero discloses an aortic catheter system for segmenting and selectively perfusing an aorta comprising: (a) an elongated shaft (30) having a proximal end and a distal end, said elongated shaft of sufficient length to be inserted into an ascending aorta and guided transluminally such that the distal end is positioned in a descending aorta when in an operative position (figs. 4-13); (b) a flow control regulator (42) positioned on said elongated shaft such that when said distal end is in the operative position said flow control regulator is capable of at least partially occluding

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the descending aorta (figs. 4-13); a perfusion pump (22 and col. 15, lines 40-47); (d) a proximal portion of said elongated shaft having a corporeal perfusion lumen (34 or 36) and an arch perfusion lumen (34 or 36), said arch perfusion lumen having a proximal end in fluid communication with said perfusion pump and dimensioned to support corporeal circulation and said arch perfusion lumen having a proximal end in fluid communication with said perfusion pump and dimensioned to support arch circulation said arch perfusion lumen terminating as at least one or more arch perfusion port proximate to a patient's arch vessels (40); and (e) a distal portion of said elongated shaft extending beyond said proximal portion, terminating as at least one or more corporeal perfusion ports (37) distal to said flow control regulator; as to claim 28, (figs. 4-13); as to claim 33; (38); as to claims 34 and 35, (42); as to claim 36, (it is the examiner's position that since applicant's and Bertolero's device are used in similar regions of the heart, then the inflated outer diameter of both balloons would be approximately the same. If this were not the case then the device of Bertolero would not work); as to claim 44, (the entire catheter (from the proximal end to the distal end) is designed to be flexible so that the catheter can bend but will not kink at body temperature); as to claim 45, (figs. 11 and 13); as to claims 46 and 47, (figs. 4-13); as to claim 73, (see above rejection; abstract and the entire specification).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertolero in view of Schiff U.S. Pat. No. 4,287,892.

Bertolero discloses an aortic catheter system substantially as claimed except for connectors that are 3/8 inch to 1/4 inch barb connectors for connection to a perfusion pump.

Schiff discloses barb connectors for connection to a pump. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Schiff to include a barb connector for respective coupling to a balloon catheter and any other tubular member coupled to a heart-lung machine (20). Additionally, it would have been an obvious matter of design choice to use various sizes of barbs, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertolero in view of Sampson U.S. Pat. No. 6,267,747.

Bertolero discloses an aortic catheter system substantially as claimed except for connectors that are 3/8 inch to 1/4 inch barb connectors for connection to a perfusion pump; said barb connector is coupled to a luer fitting.

Sampson discloses barb and luer connectors for connection to a pump. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Sampson to include a barb connector for respective coupling a balloon

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catheter to a cardiopulmonary bypass machine or any other medical device (fig. 3, 4 and 17).

Additionally, it would have been an obvious matter of design choice to use various sizes of barbs, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Furthermore, the device of Bertolero is fully capable of performing any function as disclosed by applicant.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bertolero in view of Keith et al U.S. Pat. No. 4,838,268.

Bertolero discloses an aortic catheter system substantially as claimed except for wherein said balloon has a radiopaque marker positioned within said balloon. Keith discloses a radiopaque marker positioned within the balloon (114). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Bertolero with the radiopaque marker as disclosed by Keith for locating the balloon once placed inside of the body (114).

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.



Kevin C. Sirmons
Patent Examiner
4/2/04